

AUG 09 2002

K010727

**510(k) Premarket Notification**  
**Summary of Safety and Effectiveness Information**

***Flexline™ Clamp***  
***August 8, 2002***

**Device Name:** *Flexline™ Clamp*  
**Common Name(s):** Vascular Clamp  
**Classification Name:** Clamp, vascular

**Establishment Name & Registration Number:**

**Name:** Novare Surgical Systems  
**Number:** 2954739

**Classification:**

Title 21, Code of Federal Regulations,

**§ Sec. 870.4450 Vascular clamp.**

- (a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.  
(b) Classification. Class II (performance standards).

**ProCode:** DXC

**Equivalent Device(s):**

1. The "Cosgrove Clamp", K974769, produced by Allegiance Healthcare Corporation.
2. The Slimline™ (iNtrack™ Clamp Inserts), K992640, Novare Surgical Systems, Inc.

**Description of the Device:**

The *Flexline™ Clamp* is intended for use by surgeons to temporarily occlude blood vessels in cardiovascular, peripheral vascular, and general surgical procedures. The device is constructed in such a way that the shaft of the clamp may be rigid or flexible at the discretion of the user. The clamp uses existing soft polymer jaw inserts to protect vascular tissue.

**Equivalent Device(s):**

The Allegiance Cosgrove, Slimline (now iNtrack™), and Novare's vascular clamps are all used by surgeons to temporarily occlude blood vessels during cardiovascular, peripheral vascular, and general surgery. The device labeling supports the use of these devices in the disciplines of cardiac, peripheral vascular, and general surgery. All devices are substantially equivalent in terms of materials, design, use and function.

**Applicant / Sponsor Name / Address:**

Novare Surgical Systems, Inc.  
10231 Bubb Road  
Cupertino, CA 95014  
408.873.3161

**Contact Person:**

David Danitz  
Novare Surgical Systems, Inc.  
10231 Bubb Road  
Cupertino, CA 95014  
408.873.3161

**Submission Correspondent:**

David W. Schlerf  
Buckman Company, Inc.  
200 Gregory Lane, Suite C-100  
Pleasant Hill, CA 94523-3389  
925.356.2640



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 09 2002**

Novare Surgical Systems, Inc  
Mr. David W. Schlerf  
C/O Buckman Company, Inc.  
200 Gregory Lane, Suite C-100  
Pleasant Hill, CA 94523-3389

Re: K010727  
Trade Name: Flexline Clamp  
Regulation Number: 21 CFR 870.4450  
Regulation Name: Vascular Clamp  
Regulatory Class: II  
Product Code: DXC  
Dated: May 22, 2001  
Received: May 24, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

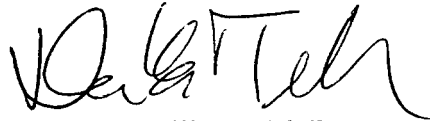
Page 2 - Mr. David W. Schlerf

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Donna-Bea Tillman', with a stylized flourish at the end.

Donna-Bea Tillman, Ph.D.  
Acting Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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510(k) NUMBER (IF KNOWN): K010727

DEVICE NAME: Flexline Clamp

INDICATIONS FOR USE:

The Flexline Clamp is used to temporarily occlude a blood vessel during cardiovascular, peripheral vascular and gastrointestinal surgery.


(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K010727